

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Fixed Orthodontic Treatment and Two Mouthrinses on Gingival Health: A Single blind placebo controlled clinical trial.

Protocol summary

Summary

In this single blind, single center and parallel randomized clinical trial study, 54 patients are randomly categorized into three groups; which are Control group, Ortho-Kin mouth rinse usage group and herbal antiseptic Persica mouth rinse. It is worth noting that each group includes 18 person. All periodontal indexes including Gingival Index (GI), Gingival Bleeding Index (GBI) and O'Leary plaque index (PI) are measured using periodontal William's probe, before starting fixed orthodontic treatment. In the first appointment, all healthy rules including the correct method of tooth brushing, the way of using dental floss and Interdental toothbrushes are trained, after placing brackets on teethes. Given periodontal indexes will be analyzed again after three months. Patients in "Ortho-Kin mouth rinse usage group" Should gurgle 15 ml mouth rinse for 30 minutes twice a day and avoid eating or drinking for about 30 minutes after applying mouth rinse (according to instruction). Patients in "Persica usage group" should instill 10 drops into spoon and then gurgle for 30 minutes three times a day (according to instruction) and patients in "Controlling group" consume placebo synthetic mouth rinse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016033024573N2**

Registration date: **2016-06-06, 1395/03/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-06, 1395/03/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-04-15, 1395/01/27

Expected recruitment end date

2016-08-15, 1395/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Fixed Orthodontic Treatment and Two Mouthrinses on Gingival Health: A Single blind placebo controlled clinical trial.

Public title

Comparing the effect of Orthokin and Persica mouthrinses on periodontal condition in fixed orthodontic patients treated in privet office in year 1395

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Patients should be under fixed double jaw orthodontic treatment; Patients should not have usage of antibiotic and mouth-rinsing experience; Patients should

not have numerous severe dental caries and/or restorations; Patients should not have severe dental plaque/ severe Gingival inflammation; Patients should not have periodontal surgery or periodontal disease experience; Patients should not have systemic disease.

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committe of Mazandaran university of medical sciences

Street address

Research Department, Moallem square, Moallem avenue, Sari, Iran.

City

Sari

Postal code**Approval date**

2016-02-15, 1394/11/26

Ethics committee reference number

IR.MAZUMS.REC.94.1217

Health conditions studied**1****Description of health condition studied**

Effect of fix orthodontic treatment and two mouthrinses on periodontal condition.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plaque index

Timepoint

Before bonding, 3 month after treatment start, 1 month after mouthrinse nad placebo

Method of measurement

Observation scoring by disclosing agent

Secondary outcomes**1****Description**

Gingival bleeding index

Timepoint

3 month after treatment

Method of measurement

Visual scale by probing

Intervention groups**1****Description**

Intervention: drug (mouth rinse) should be applied twice a day (preferably after each meal), as doses of 15 mL used for 30 seconds. Patients should avoid eating or drinking for about 30 minutes after applying mouthwash.

Category

Treatment - Drugs

2**Description**

Control: placebo solution containing 35 cc glycerine, 35 cc distilled water, and 0.3 cc ethylene blue per 100 cc.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Orthodontic, Dental Faculty, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Sepideh Dadgar and Shohreh Keikavousi

Street address**City**

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Enayati

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Research Department, Moallem square

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Orthodontics, Dental Faculty of Sari,
Mazandaran University of Medical Sciences.

Full name of responsible person

Farhad Sobouti

Position

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professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

1-The Research Council, Iranian Tissue Bank and
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Vahid Rakhshan

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty